

General

Title

Bioethics: percentage of informed written consent forms correctly filled out.

Source(s)

Quality indicators in critically ill patients. Madrid (Spain): Spanish Society of Intensive and Critical Care and Units Coronary (SEMICYUC); 2011. 185 p.

Measure Domain

Primary Measure Domain

Clinical Quality Measures: Process

Secondary Measure Domain

Does not apply to this measure

Brief Abstract

Description

This measure is used to assess the percentage of informed written consent forms correctly filled out.

Rationale

The aim of intensive care medicine is to provide critical patients with the healthcare that they need, ensuring the quality and safety of care. Intensive care medicine is one of the principal components of modern healthcare systems. There is an increasing demand for this resource, which involves high costs.

The quality of care has gradually come to be the central focus of healthcare, and in recent years patient safety has come to represent one of the key aspects of quality. In the case of intensive care medicine, this interest in quality is even more evident, not only because of its social and economic impact, but also because some of the dimensions involved in the quality of care of critical patients take on greater importance: critical patients are more vulnerable, access to critical care is more limited so efforts to distribute resources equitably are more important, scant scientific evidence is available, and the efficiency is limited.

In general, every act in a healthcare environment requires the patient's prior consent or, in the case of incapacitated patients, that of their legal

representative. Failure to obtain consent violates the patient's right to autonomy. Although, as a general rule, consent will be verbal, the legislation requires written consent in certain circumstances (surgery, invasive procedures and procedures that suppose significant risks or drawbacks).

Evidence for Rationale

Clark PA. Intensive care patients' evaluations of the informed consent process. *Dimens Crit Care Nurs*. 2007 Sep-Oct;26(5):207-26. [PubMed](#)

Davis N, Pohlman A, Gehlbach B, Kress JP, McAtee J, Herlitz J, Hall J. Improving the process of informed consent in the critically ill. *JAMA*. 2003 Apr 16;289(15):1963-8. [14 references] [PubMed](#)

Fan E, Shahid S, Kondreddi VP, Bienvenu OJ, Mendez-Tellez PA, Pronovost PJ, Needham DM. Informed consent in the critically ill: a two-step approach incorporating delirium screening. *Crit Care Med*. 2008 Jan;36(1):94-9.

Ley 41 /2002 Básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica (noviembre 2002). BOE; 2002 Nov 15.

Quality indicators in critically ill patients. Madrid (Spain): Spanish Society of Intensive and Critical Care and Units Coronary (SEMICYUC); 2011. 185 p.

Solsona JF, Cabré L, Abizanda R, Campos JM, Sainz A, Martín MC, Sánchez JM, Bouza C, Quintana M, Saralegui I, Monzó JL, y grupo de bioética de la SEMICYUC. Recomendaciones del grupo de bioética de la SEMICYUC sobre el Consentimiento Informado en UCI. *Med Intensiva*. 2002;26(5):254-5.

Primary Health Components

Bioethics; informed written consent

Denominator Description

Number of procedures requiring informed written consent (see the related "Denominator Inclusions/Exclusions" field)

Numerator Description

Number of informed written consent forms correctly filled out (see the related "Numerator Inclusions/Exclusions" field)

Evidence Supporting the Measure

Type of Evidence Supporting the Criterion of Quality for the Measure

A formal consensus procedure, involving experts in relevant clinical, methodological, public health and organizational sciences

One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

Additional Information Supporting Need for the Measure

Unspecified

Extent of Measure Testing

Unspecified

State of Use of the Measure

State of Use

Current routine use

Current Use

not defined yet

Application of the Measure in its Current Use

Measurement Setting

Hospital Inpatient

Intensive Care Units

Professionals Involved in Delivery of Health Services

not defined yet

Least Aggregated Level of Services Delivery Addressed

Single Health Care Delivery or Public Health Organizations

Statement of Acceptable Minimum Sample Size

Unspecified

Target Population Age

Age greater than or equal to 18 years

Target Population Gender

Either male or female

National Strategy for Quality Improvement in Health Care

National Quality Strategy Aim

Better Care

National Quality Strategy Priority

Person- and Family-centered Care

Prevention and Treatment of Leading Causes of Mortality

Institute of Medicine (IOM) National Health Care Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Data Collection for the Measure

Case Finding Period

Unspecified

Denominator Sampling Frame

Patients associated with provider

Denominator (Index) Event or Characteristic

Institutionalization

Therapeutic Intervention

Denominator Time Window

not defined yet

Denominator Inclusions/Exclusions

Inclusions

Number of procedures requiring informed written consent

Note:

- Procedures requiring informed written consent. The Spanish Society of Intensive and Critical Care and Units Coronary (SEMICYUC) Bioethics Work Group recommends the following
 - Tracheostomy
 - Non-urgent transfusion of blood products
 - Urgent surgical intervention
 - Renal replacement techniques
 - Non-urgent pacemaker implantation
 - Plasmapheresis
 - Angiography
- Population: All of the procedures listed above during the period reviewed.

Exclusions

Incapacitated patients whose family or legal representatives cannot be contacted

Exclusions/Exceptions

not defined yet

Numerator Inclusions/Exclusions

Inclusions

Number of informed written consent forms correctly filled out

Informed written consent forms correctly filled out: Document including the identification and signature of the physician and the patient/authorized legal representative, together with a brief description of the procedure and the possible risks involved, as well as alternatives if they exist.

Exclusions

Unspecified

Numerator Search Strategy

Institutionalization

Data Source

Electronic health/medical record

Paper medical record

Type of Health State

Does not apply to this measure

Instruments Used and/or Associated with the Measure

Unspecified

Computation of the Measure

Measure Specifies Disaggregation

Does not apply to this measure

Scoring

Rate/Proportion

Interpretation of Score

Desired value is a higher score

Allowance for Patient or Population Factors

not defined yet

Standard of Comparison

not defined yet

Prescriptive Standard

Standard: 100%

Evidence for Prescriptive Standard

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Identifying Information

Original Title

Informed written consent.

Measure Collection Name

Quality Indicators in Critically Ill Patients

Measure Set Name

Bioethics

Submitter

Spanish Society of Intensive and Critical Care and Units Coronary - Clinical Specialty Collaboration

Developer

Spanish Society of Intensive and Critical Care and Units Coronary - Clinical Specialty Collaboration

Funding Source(s)

Boehringer Laboratories

Composition of the Group that Developed the Measure

Work Group for Bioethics Work Group

- Lluís Cabré Pericas
- Koldo Martínez Urionabarrenechea
- José Luis Monzón Marín
- Miquel Nolla Salas
- Eva de Miguel Balsa
- José Julián Arias Garrido
- María Cruz Martín Delgado

Scientific Coordination:

- Maria Cruz Martín Delgado
- Jesús Blanco Varela
- Lluís Cabré Pericas
- Pedro Galdos Anuncibay
- Federico Gordo Vidal

Financial Disclosures/Other Potential Conflicts of Interest

Unspecified

Adaptation

This measure was not adapted from another source.

Date of Most Current Version in NQMC

2011 Mar

Measure Maintenance

Unspecified

Date of Next Anticipated Revision

2016 Jul

Measure Status

This is the current release of the measure.

The measure developer reaffirmed the currency of this measure in May 2016.

Measure Availability

Source available in [English](#) and [Spanish](#) from the Spanish Society of Intensive and Critical Care and Units Coronary (SEMICYUC) Web site.

For more information, contact SEMICYUC at Paseo de la Reina Cristina, 36, 4º D, Madrid, Spain; Phone: +34-91-502-12-13; Fax: +34-91-502-12-14; Web site: www.semicyuc.org ; E-mail: secretaria@semicyuc.org

NQMC Status

This NQMC summary was completed by ECRI Institute on March 19, 2014. The information was verified by the measure developer on April 25, 2014.

The information was reaffirmed by the measure developer on May 10, 2016.

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Production

Source(s)

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